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April 28, 2020

**Via ECF**

Honorable Andrew L. Carter, Jr.  
United States District Court  
Southern District of New York  
Thurgood Marshall United States Court House  
40 Foley Square  
New York, NY 10007

**Re: *Townsend v. Azar*, Case No. 20-cv-1210-ALC**

Dear Judge Carter

We represent Plaintiff Robert Townsend (“Mr. Townsend”) in the above-referenced action. Pursuant to Your Honor’s Individual Practices, we write to request a pre-motion conference related to Mr. Townsend’s anticipated motion for summary judgment.

As set forth in the Complaint and below, Mr. Townsend is appealing a denial of his claim for Medicare coverage of a device (TTFT) to treat his extremely lethal form of brain cancer. Despite having litigated – and won – the issue several times, inexplicably Defendant Alex M. Azar II, in his capacity as Secretary of the United States Department of Health and Human Services (the “Secretary”) has denied Mr. Townsend’s claim covering the months at issue as not “medically reasonable and necessary.” Because the Secretary did not appeal the prior decisions on the exact same issue and they have become final, the Secretary is collaterally estopped from denying Mr. Townsend’s claim. In light of the fact that this is an Administrative Review case that turns solely on an issue of law, with service of the Record on April 20, 2020, there is no reason to delay summary judgment briefing.

**Background on Mr. Townsend, GBM, and TTFT**

Robert Townsend is a 55-year old widower and lifelong resident of the Bronx. Prior to his diagnosis with Glioblastoma multiforme (“GBM”) in 2011, Mr. Townsend was the primary care giver to his three grandchildren. An avid sportsman and health advocate, Mr. Townsend was active in motorcycle and bicycle sports (racing and repair), volleyball, hand ball and paddle ball. Among his many activities, Mr. Townsend enjoyed kayaking on the Hudson River. Since his diagnosis, in addition to spending time with his family members, Mr. Townsend enjoys volunteering with and supporting his church.

GBM is among the most aggressive and deadly forms of brain cancer known. Without treatment, life-expectancy is three months from diagnosis. Even with surgery and chemo-radiation, average life-expectancy is 18 months and ~95% of patients have passed away within 5 years.

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More recently, treating GBM with alternating electric fields (aka Tumor Treatment Field Therapy or TTFT) has been developed. TTFT interferes with tumor cell replication and has been shown to increase the 2 year life expectancy by 38% and to nearly triple the five year survival rate. TTFT has become the standard of care for GBM in the United States. Indeed, in 2014, a clinical trial of TTFT was halted because it would have been unethical to withhold TTFT from the control group.

### **Prior Litigation**

In any Medicare coverage dispute, the basic issue is whether the device or service is a covered benefit. That conclusion is dependent on a determination that the device or service is “medically reasonable and necessary” for the beneficiary (which itself is dependent on several subsidiary questions).

Not counting the current matter, Mr. Townsend has litigated the issue of whether TTFT is a covered benefit for him three times through the Medicare appeals process. In each case, the presiding ALJ found that TTFT was “medically reasonable and necessary” to treat Mr. Townsend’s condition and a covered Medicare benefit. Thus, ALJ David Krane issued a decision on November 8, 2018, in ALJ Appeal No. 1-7737575148, finding for Mr. Townsend on all issues and ordering coverage for the months of August-October 2017. Likewise, ALJ Timothy Gates issued a decision on August 15, 2019, in ALJ Appeal No. 1-8637672132, finding for Mr. Townsend on all issues and ordering coverage for the months of November 2018-January 2019. Likewise, ALJ Carolyn Jane Van Duzer issued a decision on January 13, 2020, in ALJ Appeal No. 3-8686737932, finding for Mr. Townsend and ordering coverage for the months of February-April 2019. The Secretary did not appeal any of those decisions and they have now become final.

### **The Claim at Issue in this Case**

The claim at issue in this case is for the months of August-October 2018 (*i.e.*, the months after those at issue in ALJ Krane’s decision and immediately preceding those that are the subject ALJs Gates’ and Van Duzer’ decisions). While ALJ Krane, Gates and Van Duzer determined that TTFT was “medically reasonable and necessary” to treat Mr. Townsend’s condition and a Medicare covered benefit, ALJ Brian Butler held the exact opposite. In a decision issued on June 15, 2019 in ALJ Appeal No. 1-8429561876, despite what ALJ Butler described as “convincing evidence” that TTFT is “medically reasonable and necessary” for Mr. Townsend, ALJ Butler announced a new requirement of “uniqueness.” That is, regardless of the evidence Mr. Townsend brought forward, TTFT would be deemed not “medically reasonable and necessary,” unless Mr. Townsend could further prove that he was “uniquely positioned, when compared to other patients with the same diagnosis.” Thereafter, ALJ Butler held that TTFT is not a Medicare-covered benefit for Mr. Townsend.

On August 14, 2019, Mr. Townsend timely appealed ALJ Butler’s decision to the Medicare Appeals Council, pointing out the prior, final, favorable decisions and that the Secretary was bound by collateral estoppel. When no decision issued within 90 days as required by the statute, Mr. Townsend filed a request for “escalation” on December 13, 2019, again, noting the prior decisions and the collateral estoppel effect. When the Secretary still did not issue a decision within five days, this suit was authorized.

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**The Secretary is Barred from Denying Coverage Based on Collateral Estoppel**

Again, as set forth in the Complaint, *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held that collateral estoppel may be based on agency determinations when the agency is acting in a "judicial capacity." *See also B & B Hardware, Inc. v. Hargis Industries, Inc.*, 135 S.Ct. 1293, 1302-03 (2015) (confirming that administrative decisions can be a basis for issue preclusion). The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed.App'x. 542 (6<sup>th</sup> Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ's work determination); *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination).

Here, all the pre-requisites for applying collateral estoppel to preclude the agency from denying Mr. Townsend's claim are present. *See, e.g., In re Snyder*, 939 F.3d 92, 100 (2d Cir. 2019). The identical issue of whether TTFT is "medically reasonable and necessary" for Mr. Townsend and a covered benefit was litigated in the Krane, Gates, and Van Duzer cases and that was at issue in the Butler case. The issue was actually litigated and decided in the Krane, Gates, and Van Duzer decisions. The Secretary had a full and fair opportunity to litigate the issue in the Krane, Gates, and Van Duzer cases. Resolution of the "medically reasonable and necessary" and covered benefit issues was necessary to support the valid final judgments in the Krane, Gates, and Van Duzer cases.

Accordingly, summary judgment should be granted in Mr. Townsend's favor and his claim seeking coverage should be granted.

Respectfully submitted,

*Geoffrey Young*  
Geoffrey G. Young

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cc: All Counsel of Record (via ECF)